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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/438,365 | 11/12/1999 | Yongliang Chu | 0942.4650001 | 9217 |

7590 12/18/2001

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[REDACTED] EXAMINER

EPPS, JANET L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
| 1635 | 12 |

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | |
|------------------------------|------------------------|---------------------|
| Office Action Summary | Application No. | Applicant(s) |
| | 09/438,365 | CHU ET AL. |
| Examiner | Art Unit | |
| Janet L Epps | 1635 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 28 September 2001.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-112 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 1-9,11,15,20,21,29,42,45,48,63,70,77,93 and 95-110 is/are rejected. ⁹⁴
- 7) Claim(s) 10,12-14,16-19,22-28,43,44,46,47,49-62,64-69,71-76,78-92,111 and 112 is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Applicant's arguments with respect to claims 1-9, 29, 42, 93, and 95-109 have been considered but are moot in view of the new ground(s) of rejection. The allowability of claims 11, 15, 20-21, 45, 48, 63, 70, and 77 is withdrawn in view of the following new grounds of rejection.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 1-9, 11, 15, 20-21, 29, 42, 45, 48, 63, 70, 77, 93, and 94-110 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for synthesizing and using compounds according to the present invention wherein the Q⁺ moiety is N (nitrogen), does not reasonably provide enablement for synthesizing and using compounds wherein the Q⁺ moiety is S (sulfur) or O (oxygen). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The instant invention relates to cationic lipids and compositions for delivery of macromolecules and other compounds into cells. The specification as filed provides multiple examples wherein Applicants have synthesized compounds according to the present invention wherein said compounds has a formula according to the general formula (A; see page 6 of the specification), and wherein the Q⁺ moiety is a N (Nitrogen) group. However, Applicants have not provided one example wherein a compound according to general formula (A) is substituted

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with either O or S in the Q+ position. Furthermore, Applicants have only demonstrated the delivery of plasmid DNA into human embryonic kidney cells comprising the use of compounds wherein the Q+ moiety is N as described above. There are no examples wherein Applicants have either synthesized compounds wherein Q+ is either S or O, and further wherein Applicants have used these compounds for the delivery of macromolecules into cells. Moreover, due to the differences in the chemical properties between Oxygen, Sulfur, and Nitrogen, one of skill in the art would not accept on its face that the synthetic route for the compounds according to the present invention wherein Q+ is N is readily amenable for the synthesis of compounds wherein the Q+ moiety is either O or S. Based upon the lack of disclosure with regards to the synthetic steps required to synthesize the full breadth of compounds encompassed by the Markush structure recited in claims 1, 93, and 110, and the lack of working examples wherein Applicants have successfully synthesized compounds wherein Q+ is either S or O, and wherein Applicants have used said compounds for delivery of macromolecules in the cells, one of ordinary skill in the art would have to resort to trial and error experimentation in order to practice the full scope of the claimed invention.

The quantity of experimentation required to practice the invention as claimed would require determining the synthetic routes for isolating the full scope of the compounds encompassed by the instant claims, and further determining if said compounds are suitable as transfection agents. The specification as filed provides only guidelines with regards to substituted amine compounds according general formula (A). The deficiencies in the specification would constitute undue experimentation since the steps required for the chemical preparation of compounds according to general formula (A) wherein Q+ is either S or O, must be

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determined without instructions from the specification before one is enabled to practice the claimed invention.

4. Claims 10, 12-14, 16-19, 22-28, 43-44, 46-47, 49-62, 64-69, 71-76, 78-92, and 111-112 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

5. The prior art does not teach or suggest the specific compounds recited in claims 10, 12-14, 16-19, 22-28, 43-44, 46-47, 49-62, 64-69, 71-76, 78-92, and 111-112. See also the reasons for indication of allowable subject matter set forth in the Official Action mailed 3-28-01.

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6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps whose telephone number is 703-308-8883. The examiner can normally be reached on Mondays through Friday, 9:00AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader can be reached on (703)-308-0447. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3014 for regular communications and 703-305-7939 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

jle
December 17, 2001



SEAN McGARRY
PRIMARY EXAMINER